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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,269	12/23/2003	Kurt Nilsson	033972.549252	4452

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

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08/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,269	NILSSON, KURT	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-16 and 26-34* is/are pending in the application.

4a) Of the above claim(s) *26-29* is/are withdrawn from consideration.

5)☒ Claim(s) *33 and 34* is/are allowed.

6)☒ Claim(s) *10-16 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 04/13/09. The amendment filed 04/13/09 affects the application, 10/743,269 as follows:

1. Claims 26-29 have been withdrawn. Claims 20-25 have been canceled. New Claims 33-34 have been added.
2. The responsive to applicants' amendments is contained herein below.

Claims 10-16, 26-34 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lisman et al. (Hoppe-Seyler's Zeitschrift fuer Physiologische Chemie (1978), 359 (8), 1019-22).

Claim 10 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose, wherein the spacer comprises the following formula: $-O(CH_2)_nPhNH-$, or $-N(Ac)-(CH_2)_nNH-$, wherein n is an integer selected from 0, 1,2, 3, 4, 5, 6, or 7. Lisman et al. discloses applicant's composition comprising: a saccharide (monosaccharide) coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose (sepharose), wherein the spacer comprises the following formula: -OPhNH -, wherein n is 0 (see abstract, see also page 1020, 2nd col., 1st two paragraphs). It should be noted the O in the spacer is oxygen atom that attaches to the

monosaccharide and N in the spacer is nitrogen atom that attaches to the cross-linked agarose (sepharose) (see abstract, see also page 1020, 2nd col., 1st two paragraphs). Lisman et al. refers to the composition as sepharose-p-aminophenyl-2-acetamido-2-deoxy-β-D-glycopyranoside (see abstract, see also page 1020, 2nd col., 1st two paragraphs). Claim 11 is drawn to said composition further comprising a second spacer attached to the matrix. Lisman et al. discloses applicant's composition further comprising a second spacer (6-aminohexanoic acid) attached to the matrix (the matrix being a cross-linked agarose (sepharose)) (see abstract, see page 1020, 2nd col., 1st two paragraphs). Claim 12 is drawn to said composition wherein the matrix is bound to two or more molecules of saccharide. Lisman et al. discloses applicant's composition wherein the matrix is bound to more than one molecule of saccharide (GlcNAc) (see abstract, see page 1020, 2nd col., 1st two paragraphs). Claim 13 is drawn to said composition wherein the bound saccharide ranges from 0.01 to 20 mmole per liter of matrix. Lisman et al. discloses applicant's composition wherein the bound saccharide ranges from 2.5-3.0 mmole per liter of matrix (or 2.5 to 3.0 μmol per ml of matrix (see abstract, see page 1020, 2nd col., 1st two paragraphs). Claims 31 is drawn to said composition wherein the composition is in the form of particles, is also anticipated by Lisman et al. (see abstract, see page 1020, 2nd col., 1st two paragraphs). It should be noted that the examiner considers Lisman et al.'s composition as being in a particle form since Lisman et al.'s composition is in the form of gel (particles or beads) that is used in affinity chromatography (see abstract, see page 1020, 2nd col., 1st two paragraphs).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-16, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lisman et al. (Hoppe-Seyler's Zeitschrift fuer Physiologische Chemie (1978), 359 (8), 1019-22).

Claim 30 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; wherein the spacer comprises the following formula: -$(CH_2)_n$PhNH-, or –N(Ac)-$(CH_2)_n$NH-, wherein n is an integer selected from 0, 1,2, 3, 4, 5, 6, or 7 and wherein the bound saccharide is of specific mmole per liter of matrix. Claim 32 is drawn to said composition wherein the composition is in the form of particles.

Lisman et al. discloses applicant's composition comprising: a saccharide (monosaccharide) coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose (sepharose), wherein the spacer comprises the following formula: -OPhNH -, wherein n is 0 (see abstract, see also page 1020, 2nd col., 1st two paragraphs). It should be noted the O in the spacer is oxygen atom that attaches to the monosaccharide and N in the spacer is nitrogen atom that attaches to the cross-linked agarose (sepharose) (see abstract, see also page 1020, 2nd col., 1st two paragraphs). Lisman et al. refers to the composition as sepharose-p-aminophenyl-2-acetamido-2-deoxy-β-D-glycopyranoside (see abstract, see also page 1020, 2nd col., 1st two paragraphs).

The difference between applicant's claimed composition and Lisman et al.'s composition is the amount of bound saccharide in moles per liter of matrix.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to make adjustments to secondary parameters such as the amount of bound

saccharide in moles per liter of matrix so as to optimize the chromatographic separation or technique, or based on factors such as cost, availability and/or need.

One having ordinary skill in the art would have been motivated, to make adjustments to secondary parameters such as the amount of bound saccharide in moles per liter of matrix so as to optimize the chromatographic separation or technique, or based on factors such as cost, availability and/or need. It should also be noted that the use or preparation of said composition for said chromatographic technique is common in the art and is well within the purview of a skilled artisan. It should be noted that the examiner considers Lisman et al.'s composition as being in a particle form since Lisman et al.'s composition is in the form of gel (particles or beads) that is used in affinity chromatography (see abstract, see page 1020, 2nd col., 1st two paragraphs).

Claim 10 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose, wherein the spacer comprises the following formula: $-O(CH_2)_nPhNH-$, or $-N(Ac)-(CH_2)_nNH-$, wherein n is an integer selected from 0, 1,2, 3, 4, 5, 6, or 7. Claim 15 is drawn to said composition wherein the saccharide binds a pathogen. Claim 16 is drawn to said composition wherein the saccharide binds an antibody, a cancer-antigen, a toxin, a bacteria, or a virus. Claim 14 is drawn to said composition comprising at least one of a Blood group A determinant and a Blood group B determinant bound to matrix.

Lisman et al. discloses applicant's composition comprising: a saccharide (monosaccharide) coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose (sepharose), wherein the spacer comprises the following formula: -OPhNH

-, wherein n is 0 (see abstract, see also page 1020, 2nd col., 1st two paragraphs). It should be noted the O in the spacer is oxygen atom that attaches to the monosaccharide and N in the spacer is nitrogen atom that attaches to the cross-linked agarose (sepharose) (see abstract, see also page 1020, 2nd col., 1st two paragraphs). Lisman et al. refers to the composition as sepharose-p-aminophenyl-2-acetamido-2-deoxy-β-D-glycopyranoside (see abstract, see also page 1020, 2nd col., 1st two paragraphs). Lisman et al. use affinity chromatography separation technique that includes binding or immobilization of enzymes and substrates (see abstract, see also page 1020, 2nd col., 1st two paragraphs).

The difference between applicant's claimed composition and Lisman et al.'s composition is that applicant's composition saccharide binds a pathogen or antibody. However, it is obvious to bind a compound such as an antibody or pathogen to Lisman's et al.'s composition saccharide since Lisman et al. use affinity chromatography separation technique that includes binding or immobilization of enzymes and substrates and it is well known that affinity chromatography is a selective separation technique by which a compound (e.g., antibody) is immobilized on a polymeric matrix and used to bind selectively other compounds. In addition, it should also be noted that affinity chromatography is a chromatographic method of separating biochemical mixtures, based on a highly specific biologic interaction such as that between antigen and antibody, enzyme and substrate, or receptor and ligand. Affinity chromatography combines the size fractionation capability of gel permeation chromatography with the ability to design a stationary phase that reversibly binds to a known subset of molecules.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to use Lisman et al.'s composition to binds compounds such as a pathogen,

antigen and antibody, enzyme and substrate, or receptor and ligand based on factors such as cost, availability and/or need.

One having ordinary skill in the art would have been motivated, to use Lisman et al.'s composition to binds compounds such as a pathogen, antigen and antibody, enzyme and substrate, or receptor and ligand based on factors such as the cost, availability and/or need. It should also be noted that the use or preparation of said composition for said chromatographic technique is common in the art and is well within the purview of a skilled artisan. It should be noted that the examiner considers Lisman et al.'s composition as being in a particle form since Lisman et al.'s composition is in the form of gel (particles or beads) that is used in affinity chromatography (see abstract, see page 1020, 2nd col., 1st two paragraphs). It should also be noted that it is obvious to use Lisman's et al.'s composition in affinity chromatography separation techniques so as to include binding or immobilization of antigen such as the blood group A determinant which is one of the well established antigenic structures that consists of three sugars (oligosaccharide) and antibody or bodies specific to blood group A determinant.

Allowable Subject Matter

Claims 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The present invention relates to a material comprising saccharide-spacer-matrix where the spacer has a given formula. The saccharide-spacer-matrix or composition of claims 33 and 34 are not suggested in the prior art, nor are obvious over the prior art.

Response to Arguments

Applicant's arguments with respect to claims 10-16, 30-32 have been considered but are not found convincing.

The applicant argues that the *Lisman* material is not autoclavable as required by all of applicant's claims. However, Applicant has not provided convincing evidence that Lisman et al.'s composition or material is not autoclavable. Applicant has submitted excerpts from an article to indicate that a particular sepharose is not autoclavable. But, the Lisman's compound or composition is not simply sepharose but is is referred to as sepharose-p-aminophenyl-2-acetamido-2-deoxy-β-D-glycopyranoside (see abstract, see also page 1020, 2nd col., 1st two paragraphs). That, Applicant has not shown that sepharose-p-aminophenyl-2-acetamido-2-deoxy-β-D-glycopyranoside is not autoclavable. In fact, it is well known that sepharose compositions used in chromatographic separations techniques are autoclavable. Furthermore, it should be noted that Lisman et al.'s composition or material is the same as applicant's composition or material and consequently it should inherently have the same property of being autoclavable. Furthermore, it should be noted that the Applicant's excerpts was taken from a amersham pharmacia biootech article whereas Lisman's sepharose (not sepharose-p-aminophenyl-2-acetamido-2-deoxy-β-D-glycopyranoside) was obtained from Phagmacia Co. Uppsala, Sweden.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
August 2, 2009.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
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